

REMARKS

Claims 1-18, 20-30, 40, 43 and 53 are canceled. Claims 19 is amended herein. Support for the Amendment is found, for example, on page 17, lines 7-9 and in original claim 17. No new matter is added. Accordingly, upon entry of the Amendment, claims 19, 31-39, 41-42, 44-52 and 54 are all of the claims pending in the application before the Examiner for examination.

Response to Claim Rejections - 35 USC § 112

Claims 40-41, 50, and 54 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite. According to the Examiner, claim 40 is indefinite because it recites the composition containing additional agents while the claim that claim 40 depends from, claim 19, recites "consisting of" as the transitional phrase. The Examiner states that since "consisting of" is a close-end transitional phrase, no additional agents are permitted to be added into the composition. Therefore, by reciting "further contains ...", the metes and bounds of the claims is not clear.

Applicants submit that claim 19 is amended to include aspartame or L-menthol or aspartame and L-menthol as optional ingredients since these ingredients and claim 40 is canceled, thereby obviating this grounds for rejection. Accordingly, Applicants respectfully request withdrawal of the rejection under 35 U.S.C. § 112, 2nd paragraph, on this basis.

The Examiner further states that claims 41 and 54 recite specific dosage forms such as a solution, syrups, and tablets. However, no water, solvents, or any other pharmaceutically acceptable carriers are recited in the broadest claims 19 and 42. Therefore, it is not clear how the composition recited in claim 19 be formulated into solution, syrup, or tablets.

Applicants respectfully traverse the rejection and submit that the claims are definite as presently written. The primary purpose of the requirement for definiteness of claim language is to ensure that the scope of the claims is clear. A second purpose is to provide a clear measure of what Applicants regard as their invention so that it can be determined whether the claimed invention meets all the criteria of patentability. See MPEP § 2173.

The Examiner's focus in determining whether the claims are definite in compliance with 35 U.S.C. § 112, second paragraph should be whether the claims set out the claimed subject matter with a reasonable degree of clarity and particularity in light of (1) the content of the specification; (2) the teachings of the prior art; and (3) the claim interpretation that would be given by one of ordinary skill in the art. Therefore, definiteness of a claim must be analyzed in light of these factors and not in a vacuum. See MPEP § 2173.02. In this regard, Applicants submit that the present claims are directed to an oral administration preparation and the specification provides examples of various additives that may be employed on pages 14-16 and exemplary embodiments of the invention on pages 19-20. Thus, when properly read in light of the specification and in view of the knowledge within the art, the meaning and scope of the present claims is readily understood by one of ordinary skill in the art.

Accordingly, Applicants respectfully request withdrawal of the rejection under 35 U.S.C. § 112, 2nd paragraph, on this basis.

According to the Examiner, claim 50 recites the pH adjusting agent as a mixture; however, claim 42, from which claim 50 depending, recited "a pH adjusting agent". The Examiner states that it is not clear if the pH adjusting agents as a single compound or a mixture of compounds.

Applicants respectfully traverse this grounds for rejection on the basis that the claim language is clear to one of ordinary skill in the art. Specifically, independent claim 19 recites "a pH adjusting agent" and dependent claim 50 recites that the pH adjusting agent may be a single compound or a mixture of compounds. Thus it is clear that the pH adjusting agent may be either a single compound or a mixture of compounds. Applicants further note that claim 37 is directed to subject matter similar to claim 50 and was not rejected. Accordingly, Applicants respectfully request reconsideration and withdrawal of the rejection under 35 U.S.C. § 112, 2nd paragraph, on this basis.

Claim Rejections - 35 USC § 103

Claims 19, 31-42, 44-52 and 54 are rejected under 35 U.S.C. 103(a) as allegedly being unpatentable over the abstract of JP 8 27033 ('033) and Remington's Pharmaceutical Sciences, 18th, 1990, 1290-1292 (Remington's) in view of Merck Index, 11th ed., monograph 2279, page 354.

Applicants respectfully traverse the rejection and submit that the cited references do not teach or suggest the presently claimed invention, whether taken alone, or in combination.

In the present invention, the pH in the oral cavity is increased due to the pKa value or more of the drug to inhibit dissociation of the base and to keep its un-dissociated form (molecular type) so that the solubility of the drug in the oral cavity is reduced. In addition, the taste of the drug is changed (to the taste of oil and fat) by increasing its solubility in fat. Thus, the unpleasant taste of the drug is reduced. JP '033 and Remington neither disclose, teach or suggest the improved the claimed improved method. The Merck index also fails to remedy

these deficiencies. Thus, one of ordinary skill in the art would not have been motivated to combine the references with a reasonable expectation of achieving the presently claimed invention.

Further, the Examiner's conclusion is based on improper hindsight reasoning. As indicated by the Examiner the combination of JP '033 and Remington's does not teach or suggest the incorporation of erythritol, and a pH balancing agent as in the present claims. The Merck Index does not remedy the deficiency of the primary references, in that it also fails to teach or suggest the specific combination of a drug having a bitter taste, erythritol and a pH balancing agent as recited in independent claims 19 and 42. Even further, the references, whether taken alone or in combination, do not teach or suggest the recited amounts in dependent claims 331, 34-36, 38-39, 44, 417-49, and 51-52 or the specific ingredients recited in dependent claims 37 and 50.

In effect, the Examiner is saying that it would have been obvious for one of ordinary skill in the art to try and determine the optimum ingredients and amounts to arrive at the specific taste-masking composition of the presently claimed invention, which is contrary to the applicable law. The law states that it is not a valid basis for rejecting a claim under 35 U.S.C. § 103(a) that it was obvious to try variations to find an optimal combination. *See, e.g., In re Sigco*, 36 USPQ2d 1380, 1382 (Fed. Cir. 1995) (citing *In re Dow Chem. Co.*, 837 F.2d 469, 473, 5 USPQ2d 1521, 1532 (Fed. Cir. 1988) (rejecting the "obvious to try" standard)); *In re Deuel*, 34 USPQ2d 1210, 1216 (Fed. Cir. 1995) ("obvious to try" has long been held not to constitute obviousness").

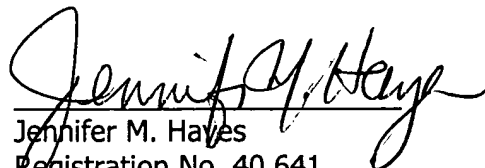
Therefore, Applicants respectfully submit that the present invention is not rendered obvious over the cited references. Accordingly, Applicants respectfully request withdrawal of the rejection under 35 U.S.C. § 103.

Conclusion

In view of the above, reconsideration and allowance of this application are now believed to be in order, and such actions are hereby solicited. If any points remain in issue which the Examiner feels may be best resolved through a personal or telephone interview, the Examiner is kindly requested to contact the undersigned at the telephone number listed below.

The USPTO is directed and authorized to charge all required fees, except for the Issue Fee and the Publication Fee, to Deposit Account No. 19-4880. Please also credit any overpayments to said Deposit Account.

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